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Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risks: Considerations for Further Action**

The following comments are from the Safe Animal Feed Education (SAFE) program in the Agricultural Commodities and Regulatory Services Branch of the California Department of Food and Agriculture (CDFA).

The Food and Drug Administration (FDA) in cooperation with state feed control programs have spent seven years on education, training, inspection and sampling emphasizing the ruminant feeding ban with an excellent level of compliance. The interim final rule on animal feed announced on January 26, 2004 to remove the current exemptions in 21 CFR 589.2000 for blood and blood products and plate waste, prohibit the use of poultry litter in ruminant feed, and require equipment, facilities, or production lines to be dedicated to nonruminant animal feed if firms use protein that is prohibited in ruminant feed, would be comprehensive and be the most enforceable BSE prevention plan for the cattle herd in the United States. In the Federal Register document Wednesday, July 14, 2004 it is stated that FDA believes these measures would serve to reduce the already small risk of BSE. If the steps in the January 26, 2004 press release were implemented then quick test kits and microscopy would allow for testing all ruminant feed that is sampled by feed control officials. Compliance with the feeding ban could be verified by a test at every facility that manufactures ruminant feed.

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm? What information is available on the occurrence of on-farm feeding errors or cross-contamination of ruminant feed with prohibited material?

The last four years CDFA has done 600 BSE inspections at dairies while performing tissue residue investigation under contract with FDA. We have observed a high level of compliance with the ruminant feeding ban and have never observed prohibited

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materials or feed containing prohibited materials on-farm at ruminant feed mixing locations.

5. What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

6. If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM-free rendered material and material rendered from SRMs?

There is no way to verify that a feed or feed ingredient does not contain specified risk material (SRM) from cattle thirty months of age or older. The possibility of cross contamination between SRM-free rendered material and SRM meat and bone meal without any way to identify the difference presents a compliance problem. If there is not an escalating level of cows contracting BSE then the feeding ban must be adequate. Taking SRM material out of all animal feed is a drastic step with little justification in a country with extremely low risk of having a cattle herd infected with BSE. In addition the disposal problem of millions of pounds of SRM and/or SRM meat and bone meal as well as improperly disposed of carcasses creates a problem with a possibility of the amplification of other disease causing pathogens.

7. What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?

Current science does not support a specified risk material (SRM) ban in all animal feed including pet food. Increased sampling and testing by the United States Department of Agriculture (USDA) has not revealed additional cattle with BSE. After the USDA has completed the sampling study of the United States (US) cattle herd, then a decision could be made on the risk of SRM from cattle over thirty months of age based on facts not politics and perception. After 220,000 to 260,000 cattle have been tested, the status of BSE in the US cattle herd will be known. The ban of all SRM material in human food will allow time for a risk assessment to be done without compromising food safety.

BSE prevention regulations involve food safety on one hand and animal health issues on the other. The ban on all SRM material in human food is an additional food safety precaution that is required so that if any BSE infected cattle pass inspection and are offered as human food, the SRM from that animal is not offered as human food. Multiple food safety firewalls should be in place to prevent variant Creutzfeldt-Jacob disease (vCJD) in humans.

9. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation? If so, what would be the scientific basis for such a prohibition?

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

16. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

17. If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

Compliance with the feeding ban for ruminant animals should continue to be the focus of the FDA and state feed control officials. Allowing meat and bone meal contained in poultry litter to be fed to ruminants because the SRM has been removed is sending the message that the feeding ban is no longer necessary. Bovine blood tested by microscopy has shown to have bone and hair in multiple samples. Plate waste may not pose a risk of BSE transmission, but from a compliance standpoint there is no way to tell the difference between meat cooked and offered for human consumption and meat processed at a rendering plant.

The ruminant feeding ban has shown to be a logical and practical way to prevent the amplification of BSE in cattle. If a BSE infected cow is rendered or SRM from an infected cow is rendered and none of this material is feed to ruminants then no additional cattle will ingest the infected tissue and the disease will not spread. If there are additional infected cattle in the United States cattle herd as they die off the disease will be self limiting and cease to exist. If increased testing of cattle known to be high risk by USDA shows an amplification of BSE in the United States then the additional measures suggested by the International Review Team should be considered.

Submitted by the Safe Animal Feed Education (SAFE) Program,
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